No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA INC.
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF FOR *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.[1] Over the past decade, hundreds of new medicines have been approved by the Food and Drug Administration ("FDA"). In view of the risky biopharmaceutical research and development process, which has a significant failure rate, and the substantial requirements of the FDA to demonstrate safety and efficacy of new products, those results are not obtained cheaply. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.[2]

PhRMA seeks to foster innovation in new medicines, including by ensuring adequate patent protection to enable and incentivize its members' substantial investments in research and development. To those ends, PhRMA seeks to remove barriers that may

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[1] Pursuant to Rule 37.6, PhRMA affirms that no counsel for a party authored this brief in whole or in part, and that no such counsel or party or person other than amicus, its members, or its counsel made any monetary contributions intended to fund the preparation or submission of this brief. The parties consented to its filing.

[2] A complete list of PhRMA members is available at http://www.phrma.org/about/members (last visited Aug. 30, 2018). Members include Eisai Inc., Petitioner's U.S. marketing partner for Aloxi®, the product at issue in this case, and Teva US Specialty Medicines, a corporate affiliate of Respondents. Neither Eisai, Inc. nor Teva US Specialty Medicines contributed any money to fund the preparation of this brief.

arise in the nation's systems, including the patent laws, for protecting the intellectual property of its members — including as *amicus curiae* before this Court.

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress amended the text of the statute defining "prior art," 35 U.S.C. § 102(a)(1), as part of the Leahy-Smith America Invents Act of 2011. The amendment affected what qualifies as prior art and what does not. One particular addition to the text, the phrase "or otherwise available to the public," specifically qualifies two categories already contained in the statute— "in public use" and "on sale." Those categories must now be read in a new light, limited by the new phrase, to encompass "in public use" and "on sale" only where that means that the claimed invention was available to the public through that public use or sale, and not where details of the claimed invention remained confidential.

The statute as amended requires that, to constitute prior art, a disclosure must put the public in possession of the claimed invention. Petitioner's private contract for the sale of its invention, at issue here, did not put the public in possession of the claimed invention because that contract was entered into with a third party bound by a promise of confidentiality as to specific features of that invention. Petitioner's subsequent patent, with claims drawn to the confidential features, therefore should not be barred.

Respondents have offered no credible alternative explanation of what change this particular amendment worked on the definition of prior art. Instead, Respondents throw up hollow arguments, such as

pressing old cases of this Court decided on several different versions of the statute going back more than two hundred years, and exaggerating Petitioner's construction of the amended statute to contrive "massive redundancies." Even though this Court's cases touching the old unqualified categories are of limited precedential value because the underlying statute itself has been amended, the Court's precedents do not support Respondents and, instead, show clear signs of pointing in the direction that the statute now clearly faces. Respondents' supposed "massive redundancies" construction results from an unreasonable reading of the statute and does not, on close inspection, create any redundancy.

The entire apparatus of the U.S. patent system has been recalibrated in accordance with the amended statute, explanations from Congress, and regulatory implementation by the United States Patent and Trademark Office, to effect what is rightly regarded as a sea change: the elimination of prior confidential activity as a determinant of patent rights. Under the new system, an inventor cannot invoke his or her own prior confidential acts to prevail in a priority contest against a rival claimant to a patent for the invention, but an inventor also need not fear that his or her own prior confidential acts would deprive him or her of a patent. The deliberate transformation of our patent system better aligns the United States with the rest of the world, promotes consistency and predictability in the administration of patent rights, and encourages early public disclosure of inventions in order best to promote the progress of science and useful arts.

ARGUMENT

I. Congress deliberately realigned the Patent Act's provisions on prior art to prevent the inventor's prior confidential activity from barring the ability to obtain a patent.

As explained in numerous other briefs in this case, the Leahy-Smith America Invents Act of 2011 was designed by Congress to transform the U.S. patent system from a first-to-invent to a first-inventor-to-file system.

The signal change required to accomplish this transformation was Congress' amendment of the definition of prior art in 35 U.S.C. § 102(a)(1) to eliminate conditions of patentability relating to confidential acts of the inventor before the filing of his patent application. *See* Pub. L. No. 112-29, § 3(b), 125 Stat. 285–86 (2011) (Leahy-Smith America Invents Act) (amending 35 U.S.C. § 102). That is, the courts and the Patent Office, in determining whether an inventor is entitled to the patent for a claimed invention, will no longer take heed of anything the inventor did confidentially before engaging the patent system. Public activities are another matter: an inventor's voluntary public disclosure of the claimed invention is prior art to a patent filed more than one year later. 35 U.S.C. § 102(b)(1). But an inventor who fails to file a patent application before another inventor independently conceives, files for, and claims the same invention can no longer invoke confidential evidence of his or her own invention, before the other's filing date, to attempt to bar the other's patent, because such confidential evidence did not apprise the public of the nature of the claimed invention. All that matters is

which filing date comes first.[3]

Similarly, where prior acts of public use or sale by an inventor do not apprise the public of the nature of the claimed invention due to, for example, confidentiality clauses, they also cannot be invoked to attempt to bar a patent. Because the claimed invention was not fully disclosed to the public, the subsequent issuance of a patent to that invention would not deprive the public of anything they already possessed. No party to this case is arguing that an open sale of a claimed invention that discloses to the public all aspects of the claimed invention and hides nothing of the invention's nature from the public cannot bar a subsequent patent. But a *confidential* sale, one that does not place the public in possession of the claimed invention, does not bar the patent under the statute as amended.

The amended statute must be interpreted to deprive an inventor of the right to rely on his or her own confidential pre-filing acts to try to bar another inventor's patent. It follows that it must also be interpreted to relieve the inventor of the burden of sacrificing his own patent due to his own confidential pre-filing acts. To do otherwise would frustrate Congress' transformation of the Patent Act into a first-inventor-to-file regime, with its exclusive reliance on disclosure to the public and filing of the patent application to define prior art. *See* Pub. L. No. 112-29, § 3(o), 125 Stat. 293 (2011) (expressing "sense of the Congress" that a first-inventor-to-file system better serves the constitutional purpose of the patent system—to "promote the progress of science and useful arts" with a limited

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[3] The Patent Act retains a provision for the inventor to challenge a fraudulent patent application that claims an invention "derived," i.e., stolen, from the inventor. 35 U.S.C. § 135 (2011).

right to exclude in exchange for full disclosure—by providing "greater certainty regarding the scope of protection" than the first-to-invent system).

The amendments to Section 102(a)(1) defining prior art share a unitary goal: to encourage public disclosure of inventions through engagement in the patent process, and thereby to build as large a body of knowledge as quickly as possible. The prohibition against an inventor's use of his or her own pre-filing confidential evidence of invention encourages early patent application filing, which eventually leads to public disclosure in a patent. The one-year grace period after public disclosure allows the inventor to gauge public opinion before committing resources to the patenting process. The elimination of the harsh aspects of the prior versions of the public-use and on-sale bars when they were applied to such uses or sales that did not make the claimed invention available to the public due, for example, to confidentiality agreements, frees the inventor from having to abandon the patent system in favor of continued secrecy after taking confidential initial steps toward commercialization.

II. Petitioner's correct interpretation of "otherwise available to the public" in amended Section 102(a)(1) does not create redundancy within the definition of prior art.

The amended statutory text lists three categories of prior art that bar issuance of a patent if the claimed invention was, before its effective filing date:

- "patented,"
- "described in a printed publication," or
- "in public use, on sale, or otherwise available to the public."

35 U.S.C. § 102(a)(1). Respondents argue that the phrase "otherwise available to public" in the third category must be interpreted to modify nothing at all because any other interpretation results in "massive redundancies," whether it is held to apply to the two subcategories of "in public use" and "on sale" in the third category , or to all three categories in their entirety. Br. in Opp. 3–4 (internal quotation marks omitted).

But Congress's use of "otherwise available to the public" in its amendment of Section 102(a)(1) has meaning that distinguishes, on the one hand, items in the other two subcategories of the third category, *i.e.*, acts of public use and acts of being on sale, when they provide details sufficient to make available to the public the claimed invention itself, from, on the other hand, such acts that do not provide sufficient detail to make the claimed invention available to the public. In the first instance, making "available to the public" details adequate to disclose the claimed invention means that the disclosure constitutes prior art that will not allow a later patent to remove that knowledge from the public domain. But, in the second instance, the less-than-full disclosure does not constitute prior art that bars issuance of a patent because the claimed invention, itself, has not become public knowledge.

As Petitioner explains in its principal brief, the phrase "otherwise available to the public" is properly construed to qualify the scope of "in public use" and "on sale" because all three are subcategories in the third category and grammar conventions show that the third category is set apart by the use of "or" from the other two categories. Pet. Br. 18–25. Respondents

argue that because this interpretation applies "otherwise available to the public" to "in public use," it must be redundant. Br. in Opp. 3.

Respondents are wrong in their claim that this interpretation creates redundancy. An item in public use might, nonetheless, conceal the claimed invention and therefore not be available to the public. Such uses are described by the Government as "secret public use." Gov't C.A. Br. 7–8. As Senator Kyl explained in his floor statement, Congress considered cases to be extreme when they treated public uses as prior art to void a patent even though the public use did not make the claimed invention available to the public. 157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011) (statement of Senator Kyl) (citing, *e.g.*, *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881) (corset worn in public but concealed by clothing nevertheless a patent-barring public use)). Cases such as *Egbert* are "extreme" because they punish inventors by denying them patents for acts that, though committed in public, nevertheless still concealed from the public the nature of the invention. 157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011). Congress intended to exclude such "extreme results" from the AIA definition of prior art and to limit the scope of prior art in public use that bars a patent to public uses that put the public in possession of the claimed invention before the patent application is filed. *Id.*

Applying "otherwise available to the public" to "on sale" similarly is not redundant; an item can be on sale and yet not make the claimed invention available to the public. The Federal Circuit recognized, for example, that whether the details of an invention are revealed to the public, or kept confidential, in the course of a sale was a "factor" in determining whether the sale triggers a bar under Section 102 prior to its

amendment by the Leahy-Smith America Invents Act. *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363, 1376 (Fed. Cir. 2016) (en banc). As discussed in the next section, this Court has never ruled on the question but has intimated that a secret public use should not be a bar. In any event, Section 102(a)(1), as amended, draws a distinction between sales that make the claimed invention "available to the public" and sales that do not. A sale which reveals to the public the details of the claimed invention bars a patent, while sales that withhold details do not, because they do not render the details accessible to the public.

In the present case, although the sale revealed to the public many details of the invention, it is undisputed that the sale required the parties to keep confidential at least one significant feature recited in the claim: the dosage. Pet. Br. 13. Thus the public, with full knowledge of the sale and all publicly-released details of the transaction, still would not have known what the invention was, because the claimed dosage and formulation were kept confidential.

III. This Court's precedents point toward limiting the "on sale" bar to public availability.

Respondents make much of the long history of the on-sale bar in this Court but fail to identify a single case in which this Court affirmed the invalidation of a patent in which a prior sale kept confidential from the public some facet of the claimed invention.

Prior versions of the statute were silent as to whether a confidential sale violated the on-sale bar, and this Court did not have occasion to resolve the issue. But in rendering decisions in numerous on sale and public use cases, this Court did suggest repeatedly that the bar against issuance of a patent is

triggered when the sale or use of the invention reveals the nature of the claimed invention to the public, because only then would issuance of the patent remove something from public knowledge.

This suggestion permeates the cases that Respondents cite, beginning with *Pennock v. Dialogue*, 27 U.S. 1 (1829), in which this Court applied the Patent Act of 1793. The patent in that case concerned an improved hose that was openly and publicly used such that the claimed invention would have been apparent to the public for years before patenting. *Pennock*, 27 U.S. at 3. The nature of the invention in *Pennock*—hose made more watertight by overlapping hose segments and riveting them together, rather than stitching them end-to-end—would have been immediately apparent to an observer; nothing in this Court's opinion or in the circuit court's opinion suggests otherwise. *See Pennock v. Dialogue*, 19 F. Cas. 171, 171 (C.C.E.D. Pa. 1825) (circuit court decision describing invention).[4] The Court explained that "the first inventor cannot acquire a good title to a patent; if he suffers the thing invented to go into public use, or to be *publicly* sold for use, before he makes application for a patent." *Pennock*, 27 U.S. at 23–24 (emphasis added). Thus even this nascent form of the on-sale bar tethered the sale to some public-facing disclosure. The next case Respondents cite, *Shaw v. Cooper*, quotes exactly this passage from *Pennock* in holding that the invention's "use by the public" before the patent application invalidated the patent. *Shaw*

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[4] Respondents assert that Pennock's hose joints "did not reveal the process" of their manufacture, Br. in Opp. 5, but offers no citation to the *Pennock* opinion or other explanation to substantiate this assertion.

v. Cooper, 32 U.S. 292, 318 (1833) (cited at Br. in Opp. 6).

Respondent's next two cases, *Kendall v. Windsor* and *Egbert v. Lippmann*, are inapposite to the present issue. *Kendall* concerned a trade-secret misappropriation by a non-inventor employee who had been pledged to secrecy. *Kendall v. Windsor*, 62 U.S. 322, 324–25 (1858) (cited at Br. in Opp. 6, 31). The trial court had found that "it did not appear any sale of the thing patented had been made." *Id.* at 327. The Court cited *Pennock* and *Shaw* merely to contrast the involuntary disclosure in *Kendall* from the voluntary, and patent-barring public use, in the earlier cases. *Id.* at 329–31. Because *Kendall* did not involve a voluntary public use, any broad pronouncements as to the nature of the public use or on-sale bar are dicta.[5] *Egbert*, as Respondents readily acknowledge, involved a gift of the invention to a recipient for use "without restriction or limitation." *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881) (cited at Br. in Opp. 7, 21, 23). Nor did *Egbert* involve a sale. Its pronouncements touching the on-sale bar, like *Kendall*, are therefore dicta.

The final decision of this Court on which Respondents rely, *Pfaff v. Wells*, similarly took a cue from earlier decisions in expressing concern that an inventor should not be allowed "to remove existing knowledge from public use" by seeking a patent after a sale. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998)

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[5] This Court has expressed skepticism toward relying on "broad declarations" of legal principles expressed in its earlier decisions under obsolete versions of the Patent Act. *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 584 U.S. ---, sl. op. at 11 (2018).

(cited at Br. in Opp. 6, 7, 8, 31, 32). The Court's decision does not address whether the sale at issue was confidential as to the details of the claimed invention.

None of these cases addresses whether a sale of the invention, the terms of which sale bind the parties to confidentiality, bars a subsequent patent to the invention. Rather, the cases contain numerous suggestions that the touchstone for application of the bar is the public, non-confidential, and unrestricted disclosure of the claimed invention so that it is made available to the public. Congress, acting on those suggestions, amended the statute to require that issuance of a patent is barred by an earlier sale only if that sale revealed the claimed invention to the public, not if that sale was shrouded in confidentiality.

CONCLUSION

The judgment of the Court of Appeals should be reversed.

Respectfully submitted,

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